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**REMARKS** 

The Amendment

Claim 1 is amended to delete Formulae I, III and IV in response to the Restriction

Requirement.

Claims 4-8 are amended to provide proper claim language, which clarifies the meaning of

the claims.

No new matter is added in any of the above amendments. The Examiner is requested to

enter the amendment and reconsider the application.

The Remarks

**Election/Restriction** 

The Examiner states that Applicant has elected without traverse of Group II, wherein X is

oxygen, m+n=2, and B and B' are a pyrimidine of general formula IIb.

Although Applicant has elected X = oxygen; m+n = 2; B and B' are each independently a

pyrimidine of general Formula IIb in response to the species election requirement, upon the

allowance of a generic claim, Applicants will be entitled to consideration of claims to additional

species which are written in dependent form or otherwise include all the limitations of an

allowed generic claim as provided by 37 CFR §1.141.

35 U.S.C. §112, Second Paragraph Rejection

Claims 1-5, 8, and 10-11 are rejected under 35 U.S.C. §112, second paragraph as

allegedly being indefinite for failing to particularly point out and distinctly claim the subject

matter which Applicants regard as the invention.

The Examiner states that the term "effective amount" has been held to be indefinite when

the claim fails to state the function which is to be achieved and more than one effect can be

implied from the specification or the relevant art. Applicant has amended Claim 1 to recite that

whereby said preparation is effective on promoting tear secretion and mucin production in the

eyes in a subject. Applicant has also amended Claims 10 and 11 to recite an effective amount to

promote tear secretion and mucin production in the eyes.

The Examiner states that there is insufficient antecedent basis for the limitations drawn to

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the administration of the compound to places other than the eyes in claims 4, 5 and 8. Applicant has amended the claims to clarify the claim language. The dinucleotide compound is indirectly administered to the eyes via systemic absorption and circulation in Claims 4 and 5. Claim 8 is amended to delete "systemic" and to depend upon Claim 1.

In view of the amendment, the Examiner is requested to withdraw the §112, second paragraph rejection of Claims 1-5, 8 and 10-11.

## **Double Patenting Rejection**

Claims 1-11 are rejected under 35 U.S.C. §101 as allegedly claiming the same invention as that of Claims 1-9 of prior U.S. Patent No. 5,900,407. The rejection is traversed because the claims in the present application are not the same as those in the '407 Patent.

MPEP 804 IIA states that:

A reliable test for double patenting under 35 U.S.C. 101 is whether a claim in the application could be literally infringed without literally infringing a corresponding claim in the patent. In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970). Is there an embodiment of the invention that falls within the scope of one claim, but not the other? If there is such an embodiment, then identical subject matter is not defined by both claims and statutory double patenting would not exist. For example, the invention defined by a claim reciting a compound having a "halogen" substituent is not identical to or substantively the same as a claim reciting the same compound except having a "chlorine" substituent in place of the halogen because "halogen" is broader than "chlorine."

The claim scope of the '407 Patent includes Formula I, II, III and IV; whereas the claim scope of the instant application includes only Formula II. Therefore, the claims in the '407 Patent are not identical to or substantively the same as the instant claims.

Therefore, the 35 U.S.C. §101 rejection of Claims 1-11 should be withdrawn.

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## **CONCLUSION**

Applicants believe that the application is in good and proper condition for allowance. Early notification of allowance is earnestly solicited. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 463-8109.

Respectfully submitted,

Date: December 17, 2003

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